GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:586
ANSWERED ON:26.02.2016
Pharmaceutical Research Companies
Rao (Avnthi) Shri Muthamsetti Srinivasa

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the pharmaceutical research companies/laboratories are resorting to unethical practices in conducting clinical trial and keeping the volunteers in dark about the side effects;

(b) if so, the details thereof, State/UTwise including Telangana, Andhra Pradesh and Maharashtra;

(c) whether the mandatory Ethics Committee framed under the Clinical Establishment Act, 2010 has remained spectator of violations of rules by the pharmaceutical research companies/ laboratories; and

(d) if so, the details thereof and the reasons therefor and the action taken by the Government against such pharmaceutical research companies/ laboratories?

Answer

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)
(a) & (b): As per Drugs and Cosmetics Rules. 1945 every clinical trial participant has to give informed consent. The sponsor/ investigator are duty bound to administer the consent to Clinical trial participants and informed consent document inter alia includes the following elements viz.
(i) description of any reasonably foreseeable risk or discomfort to the subject; and

(ii) a statement that particular treatment or procedure may involve risk to the subject (or to embryo or foetus, if the subject is or may became pregnant), which are currently unforeseeable.
Accordingly, any violation of the aforesaid rule entails action against the violator. The Central Drugs Standard Control Organisation (CDSCO) conducts inspection of various clinical trial. Based on the inspection findings, action is taken as per the provisions of the Drugs and Cosmetics Rules, 1945.

(c): The Clinical Establishment (Registration and Regulation) Act, 2010 does not cover the subject of Ethics Committees.

(d): Does not arise.